

### **REMARKS**

Claims 1-33 have been canceled. New claims 34 to 42 are pending.

### **THE INVENTION**

Applicant's invention provides devices for treating tissue affected by disease, such as ischemia, by delivering therapeutic substances in combination with angiogenic implants. The subject matter now claimed is directed to the combination of an implant in the form of a scaffold implantable to be retained within tissue and having a structure configured to mechanically trigger an injury response in the tissue that leads to angiogenesis, coupled with thrombus associated with the implant and loaded with therapeutic material to provide a host matrix for the therapeutic material.

### **APPLICANT'S COMMENTS WITH RESPECT TO THE PREVIOUSLY CITED PRIOR ART**

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#### **Gambale *et al.* (U.S. Pat. No. 6,432,126; "Gambale")**

Gambale discloses implants and delivery systems for promoting angiogenesis in ischemic tissue. The implants can be implanted into the myocardium. The implants can be a capsule (*e.g.* Figs. 1A-B, 2A-C), a fabric-covered tube (*e.g.*, Figs. 6A-C, 7A-B), or a porous tube (Figs. 8A-E).

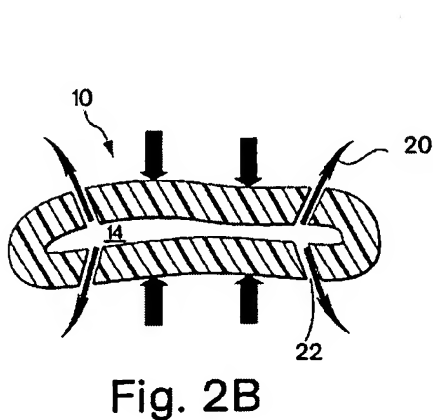


Fig. 2B

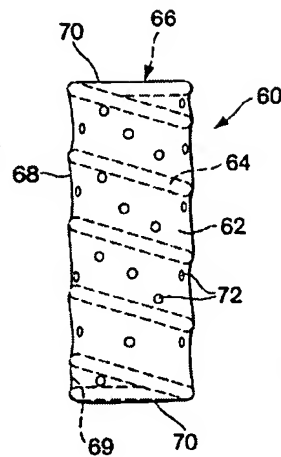


Fig. 6A

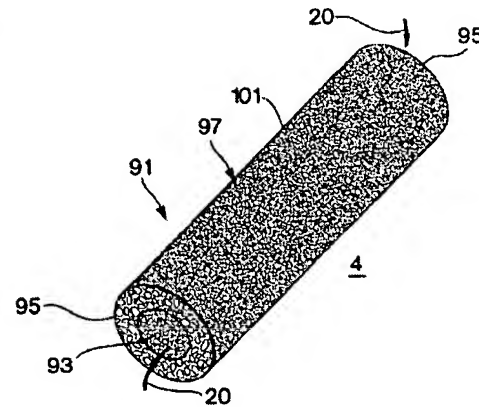


Fig. 8A

The implants are configured to be flexible so that they compress and expand with movement of the surrounding tissue. Blood flows in and out of the implant as it is compressed and expands. The flow of blood into the implant and pooling in the implant causes formation of thromboses and fibrin growth. This leads to angiogenesis in the surrounding tissue.

The implants can also contain an angiogenic substance or a thrombus, which can be preloaded or injected into the device after implantation. There is no suggestion of a therapeutic substance or a therapeutic substance loaded into thrombus. At any rate Gambale '126 is not prior art to the present application under 35 U.S.C. §103. At the time of filing of both the present application and the Gambale patent, the inventors of each were subject to an obligation to assign to C.R. Bard. According to 35 U.S.C. §103(c)(1), subject matter developed by another person, which qualifies as prior art under 35 U.S.C. §102(e), shall not preclude patentability where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

**Cafferata (U.S. Pat. No. 6,689,121; "Cafferata")**

Cafferata discloses a system and method for implanting pellets into myocardial tissue for treatment of disease. The pellets can be spherical or conical, and serve as depots, delivering medication to the area in which they are implanted. The medication can be a pharmaceutical, a

viral or non-viral vector, cells, plasmid-liposome complexes, DNA delivery complexes, oligonucleotides, etc. There is no mention of thrombus.

**Slepian *et al.* (U.S. Pat. No. 5,575,815; "Slepian")**

Slepian discloses a method for providing a synthetic barrier made of biocompatible polymeric materials *in vivo*. The material is applied in a fluid state to a tissue or a cellular surface (such as the interior of the blood vessel). It adheres to the tissue surface, and is then converted to a non-fluid state.

Respectfully submitted,



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